K033525

JAN 1 2 2004

# Summary of Safety and Effectiveness Information

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR§807.92.

**Submitter's Name:**

Richard M. Vaught
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714-6101

**Date of Preparation:** November 6, 2003

**Name of Product(s):** Dimension® Microalbumin (MALB) Flex® reagent cartridge (DF114)
and
Dimension® Microalbumin Calibrator (DC114)

**FDA Classification Name(s):** Albumin test system (21CFR§866.5040)
Calibrator (21CFR§862.1150)

**Predicate Device(s):**

Method: Other commercially available urinary albumin assay systems such as the Dade Behring nephelometric (BN II) N Antiserum to Human Albumin assay (K972929).

Calibrator: Other commercially available calibrators such as the Dade Behring Urinary Albumin Calibrator (K936201).

**Device Description(s):**

Method

The Microalbumin (MALB) method (DF114) is based on a particle-enhanced turbidimetric inhibition immunoassay (PETINIA) adapted to the Dimension® clinical chemistry system which allows direct quantitation of albumin in urine samples. The MALB Flex® reagent cartridge contains a particle reagent (PR) consisting of latex particles with human albumin bound to the surface. Aggregates of these particles are formed when a monoclonal antibody (Ab) to human albumin is introduced. Albumin (ALB) present in the sample competes with the particles for the antibody, thereby decreasing the rate of aggregation. Hence, the rate of aggregation is inversely proportional to the concentration of albumin in the sample. The rate of aggregation is measured

using bichromatic turbidimetric reading at 340 and 700 nm. The concentration is determined by means of a mathematical function.

$$PR + Ab + ALB\ (sample) \rightarrow PR\text{-}Ab\ Complex + Ab\text{-}ALB$$
(scatters at 340 nm)

Calibrator
The Dade Behring Dimension® Microabumin Calibrator (DC114) is a buffered aqueous product containing weighed-in quantities of human albumin. The calibrator is packaged as a 5-level kit at nominal albumin concentrations of 0, 12.5, 25, 50, and 110 mg/L.

**Intended Use:**

Method
The Dade Behring Dimension® Microalbumin (MALB) Flex® reagent cartridge method is an *in vitro* diagnostic test intended to quantitatively measure albumin in human urine.

Calibrator
The Dade Behring Dimension® Microalbumin Calibrator is an *in vitro* diagnostic product used to calibrate the Microalbumin (MALB) method on Dade Behring Dimension® clinical chemistry systems.

**Comparison to Predicate:**

Split-sample comparative performance was evaluated at Dade Behring between the Dimension® MALB Flex® reagent cartridge method assay system and the BN II nephelometric N Antiserum to Human Albumin assay. The results are summarized below:

| Comparative Method | Slope | Intercept (mg/L) | Correlation Coefficient | n |
|---|---|---|---|---|
| N Antiserum to Human Albumin (Dade Behring BN II) | 0.97 | 0.45 | 0.999 | 50 |

**Comments on Substantial Equivalence:**
Both Dade Behring albumin assay systems - the Dimension® Microalbumin (MALB) Flex® reagent cartridge method and the BN II nephelometric N Antiserum to Human Albumin are intended for determination of albumin in urine. Split-sample comparative data demonstrate

good agreement (correlation) between the methods. Both products utilize light scattering detection techniques for the measurement of albumin.

**Conclusion:**

The Dade Behring Dimension® Microalbumin (MALB) Flex® reagent cartridge method (DF114) and the Dade Behring BN II nephelometric N Antiserum to Human Albumin assay are substantially equivalent based on their intended purpose, design and the comparison performance results as described earlier. Also, the Dade Behring Dimension® Microalbumin Calibrator (DC114) is substantially equivalent to other calibrators, such as the Dade Behring Urinary Albumin Calibrator based on its design and intended purpose.

Richard M. Vaught
Regulatory Affairs and Compliance Manager
November 6, 2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 12 2004

Mr. Richard M. Vaught
Regulatory Affairs and Compliance Manager
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714

Re: k033525
Trade/Device Name: Dimension® Microalbumin (MALB) Flex® reagent cartridge (DF114)
Dimension® Microalbumin Calibrator (DC114)
Regulation Number: 21 CFR 866.5040
Regulation Name: Albumin immunological test system
Regulatory Class: Class II
Product Code: DCF; JIT
Dated: November 6, 2003
Received: November 7, 2003

Dear Mr. Vaught:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Recd 1-6-04

# Indications For Use Statement

**Device Name(s):**

Dimension® Microalbumin (MALB) Flex® reagent cartridge (DF114)

Dimension® Microalbumin Calibrator (DC114)

**Indications for Use:**

The Dade Behring Dimension® Microalbumin (MALB) Flex® reagent cartridge method is an *in vitro* diagnostic test intended to quantitatively measure albumin in human urine. Measurement of albumin aids in the diagnosis of kidney and intestinal diseases. Measurement also aids in the diagnosis and treatment of heart diseases or thyroid disorders which are characterized by proteinuria or albuminuria.

The Dade Behring Dimension® Microalbumin Calibrator is an *in vitro* diagnostic device intended for use on Dade Behring Dimension® clinical chemistry systems for medical purposes to establish points of reference that are used in the determination of albumin in urine.

Richard M. Vaught
Regulatory Affairs and Compliance Manager

January 5, 2004

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

**Prescription Use** ✓ **OR** **Over-the-counter Use**_____
**(Per 21 CFR 801.109)**

**(Optional format 1-2-96)**

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033525